Pharmacia & Upjohn

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Global Regulatory Affairs
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May 24, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Subject: **[Docket No. 99D-0484]** Draft Guidance for Industry on Accelerated Approval Products: Submission of Promotional Materials

Dear Sir/Madam,

Pharmacia & Upjohn would like to make the following comments and suggestions in response to the Notice published in the Federal Register on March 26, 1999, announcing availability of the subject guidance document.

Section V of the draft guidance indicates that "derivative" promotional materials intended for use after the 120-day post-approval period should be submitted to the FDA for review prior to use. In our opinion, pre-clearance of derivative materials is an inefficient and unnecessary use of both FDA and sponsor resources. Consequently, we urge the FDA to consider deleting this requirement from the final guidance document, replacing it with a statement that limits submission of derivative materials to the post-marketing report requirements in 21 CFR 314.81(b)(3)(i). Our opinion is based on the following.

1. The draft guidance defines derivative promotional materials as "materials that present product claims and representations of the same content and context as previously reviewed materials." This definition establishes clear boundaries within which the promotional messages conveyed by a derivative piece remain unchanged from previous materials pre-cleared by the agency. In our opinion, this provides sufficient guidance to help sponsors determine the type of information that may appropriately be included in derivative materials without the need for pre-clearance by the agency. While we believe that the risks are minimal, any misinterpretation of this definition resulting in the dissemination of potentially violative materials should be adequately controlled by FDA's routine review of materials submitted under the post-marketing report requirements in 21 CFR 314.81(b)(3)(i).

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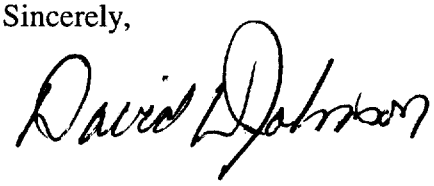
2. Based on the definition described above, there is a low probability that derivative materials will contain truly false or misleading information at the time of submission. In our opinion, the additional staff time required by both FDA and the sponsor to prepare, file, review and formally respond to a pre-clearance submission is not justified by the small, incremental reduction in risk that may be provided by the pre-clearance requirement for derivative materials. As indicated above, we believe that FDA's routine review of derivative materials submitted under the post-marketing report requirements in 21 CFR 314.81(b)(3)(i) should provide adequate assurance that violative materials are not being disseminated. In addition, the time saved by eliminating the pre-clearance requirement for derivative materials could be better spent on higher priority activities, such as the review of launch materials for new products.

We appreciate the opportunity to comment on this draft guidance and hope that the suggestions outlined above will provide useful input during development of the final guidance document.

Sincerely,



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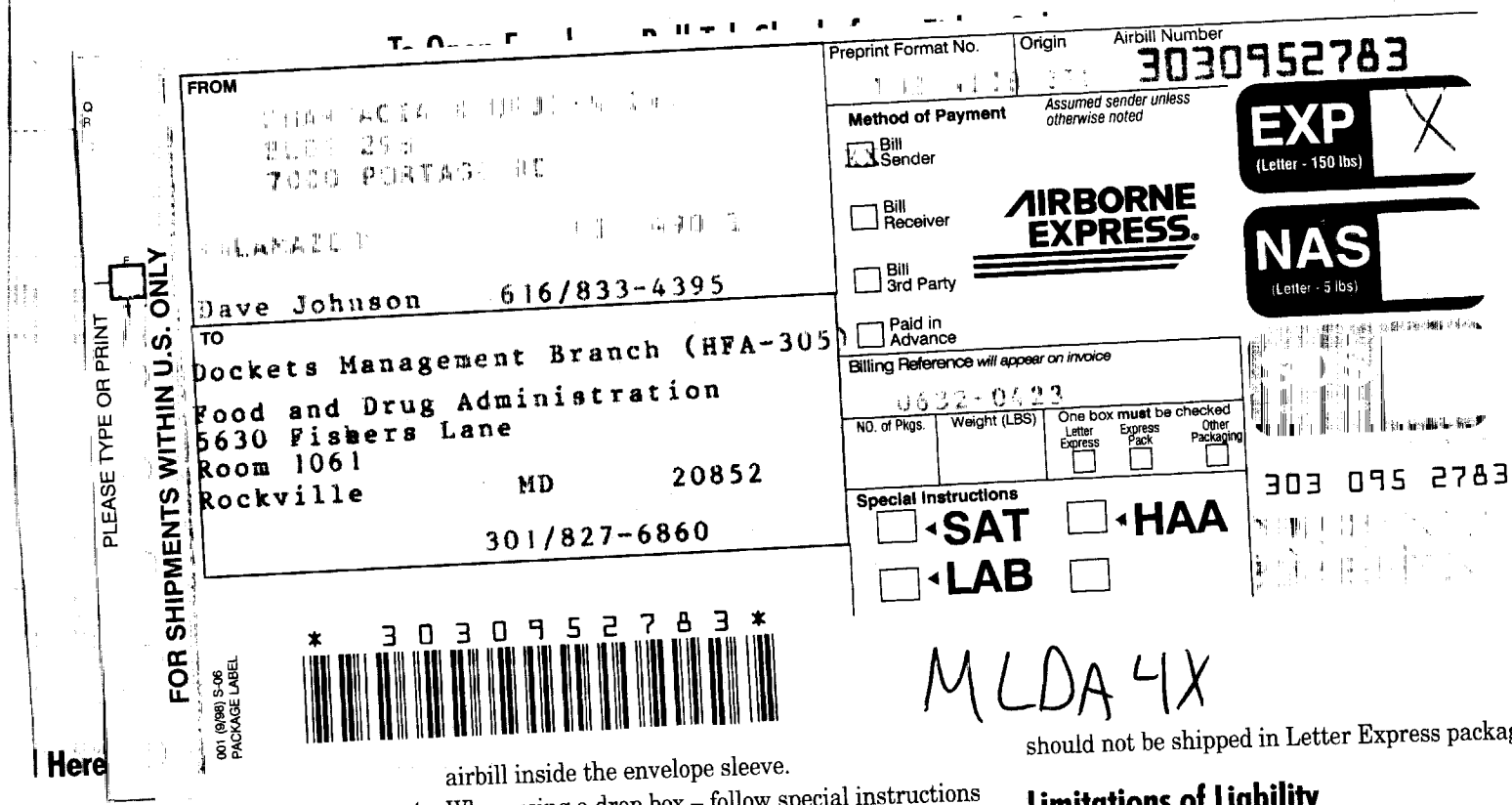

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